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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,736	08/11/2005	Mara Brancaccio	4636-25	7505

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
GEMENIANO, MALOU C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/538,736	BRANCACCIO ET AL.	
	Examiner	Art Unit	
	Malou C. Gemeniano	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-17 and 20-21, drawn to a non-human transgenic animal with an altered expression of melusin and the cell from the non-human transgenic animal having an altered melusin expression.

Group 2, claims 18 and 23, drawn to a method for the selection of compounds pharmacologically active in the prevention and/or treatment of heart failure.

Group 3, claim 19, drawn to a method for studying heart pathologies.

Group 4, claims 24 and 25, drawn to a method for preparing a non-human transgenic animal

Group 5, claim 26, drawn to non-human animals whereby the melusin function has been inhibited by the use of natural or synthetic compounds.

Group 6, claim 27, drawn to a method to study impaired cardiac hypertrophy

Group 7, claim 28, drawn to a method to study cardiac dilation

Group 8, claim 29, drawn to a method to study heart failure

Group 9, claim 30, drawn to a method for screening compound that interact with melusin binding proteins

Group 10, claim 31, drawn to a method for screening compound that interact with melusin.

Group 11, claim 32, drawn to a method of use of melusin, fragments and derivative thereof as medicant for the prevention and/or treatment of heart failure.

Group 12, claim 33-35, drawn to a method of use of melusin, fragments and derivative thereof to screen compounds pharmacologically active for the prevention and/or treatment of heart failure

Group 13, claim 36-37, drawn to a method of use of a vector expressing melusin.

If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is drawn to a non-human transgenic animal and a cell with an altered expression of melusin. The technical feature of Group 5 is a non-human animal whereby the melusin is inhibited by a compound. Groups 2-4 and 6-13 are drawn to multiple distinct methods of use and multiple distinct products that do not share the same inventive concept with each other as well as the products of Group I and 5. The claimed inventions of Groups 2-4 and 6-13 recite distinct materials and/or method steps that are do not require the claimed invention of Group I and 5, and thus have their own technical features, e.g. a method for the selection of compounds pharmacologically active in the prevention and/or treatment of heart failure (Group 2), method for studying heart pathologies (Group 3), drawn to a method for preparing a non-human transgenic animal (Group 4), drawn to a method to study impaired cardiac hypertrophy (Group 6), drawn to a method to study cardiac dilation (Group7), drawn to a method to study heart failure(Group 8), drawn to a method for screening compound that interact with melusin binding proteins (Group 9), drawn to a method for screening compound that interact with melusin. (Group 10), drawn to a method of use of melusin, fragments and derivative thereof as medicant for the prevention and/or treatment of heart failure (Group11), drawn to a method of use of melusin, fragments and derivative

thereof to screen compounds pharmacologically active for the prevention and/or treatment of heart failure (Group 12) and drawn to a method of use of a vector expressing melusin (Group 13), Further, each of the groups has a technical feature not required for the other groups. For example, the method for selecting compounds pharmacologically active in prevention and/or treatment of heart failure of Group 2 is not required for the method for preparing a non-human transgenic animal of Group 4. The Groups are also distinct inventions because the method inventions can be performed using other and materially distinct products, such as cell from a patient or a non-transgenic animal that has naturally-occurring mutations of melusin. In addition, transgenic can be used for processes other than the methods of the claimed inventions, such as in breeding with other animals. Furthermore, because these methods have such divergent purposes and functions as well as effects, the search for one method would not be co-extensive with another method. For example, group 8 is drawn to a method to study heart failure while group 4 is a method pertaining to a method for preparing a non-human transgenic animal. In this instant, these methods uses different starting material as well have different effects and objective. The scope of group 8 does not over lap with the scope of group 4; therefore, their searches would not be co-extensive and would be undue burden to perform a search the products and methods group together or any combination thereof.

Each invention is directed to a distinct goal, which comprises the use of separate products or methods in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups 1 to 13 do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

Should Applicant elect Group 1, Applicant is required to further elect from the following groups as recited in claim 2:

1(a) altered melusin expression due to stable expression

1(b) altered melusin expression due to transient expression

The inventions listed as Groups 1(a) and 1(b) do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example the technical feature for group 1a is that the expression is due the integration of DNA into the genomic DNA such that integrated DNA is continually propagated with every round of replication and continually expressed in progeny cells which is technically distinct from transient expression recited in group 1(b) in which the DNA can exist episomally in the cell and never integrate into the genomic DNA. In addition the scope of these groups are different and the search for group 1(a) will result in a list of non-patent literature that is distinct and different from the list search for group 1(b); therefore, would be an undue search burden to search these groups together. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups 1a to 1b do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

Should Applicant elect either Group 1a or Group 1b, Applicant is required to further elect from the following groups as recited in claim 2:

(i) modification of expression is at the transcriptional level

(ii) modification of expression is at the translational level

(iii) modification of expression is at the post-translational level

The inventions listed as Groups (i), (ii) and (iii) do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example the technical feature for Group (i) is that the modification is at the transcriptional level while Group (ii), modification is at the translational level and Group (iii), modification is at the post-translation level. The technical feature of these Groups are distinct inventions requiring very different material. For example, modification on the transcriptional level requires RNA polymerase, DNA binding proteins and transcriptional factors, modification on the translational level requires ribosomes and ribosome binding sites and modification on the post-translation requires many of the post-translational machinery such as glycosylation, phosphorylation and myristylation etc. In addition the scope of these groups are

different and the search for group (i) will result in a list of non-patent literature that is distinct and different from the list search for group (ii) or (iii); therefore, would be an undue search burden to search these groups together. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups (i)-(iii) do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

Should Applicant elect either Group 12 Applicant is required to further elect from the following groups as recited in claim 33:

(i) a compound is a melusin agonist

(ii) a compound that interacts with melusin-binding protein

The inventions listed as Groups (i) and (ii) and do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. In the instant case, both Group (i) and (ii) are drawn to an unspecified compounds that are reasonably distinct structurally and functionally, especially when the unspecified compound of Group (i) is a protein and the unspecified compound of Group (ii) is a nucleotide. In this instant case, proteins, which are composed of amino acids, polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. In addition the scope of these groups are different and the search for group (i) will result in a list of non-patent literature that is distinct and different from the list search for group (ii); therefore, would be an undue search burden to search these groups together. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups (i)-(ii) do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

In addition, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to further elect from the following species of mice strains as recited in claim 17: a) strain 129SV b) C57B1 c) 129SV x C57B1

Applicant is required to further elect from the following species of viral vectors as recited in claim 38: a) adenoviral vector b) lentiviral vector.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 17 and claims dependent therefrom correspond to all species list above.
The following claim(s) are generic: claim 16

Claim 38 and claims dependent therefrom correspond to all species list above.
The following claim(s) are generic: claim 36

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features.

Applicant is advised that the reply for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malou C. Gemeniano whose telephone number is 571-272-6451. The examiner can normally be reached on 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jabobs, whose telephone number is (571)-272-0532.

For all other customer support, please call the USPTO Call Center (UCC) at (800)-786-9199.

Malou C. Gemeniano, Ph.D
Examiner, USPTO, AU 1632

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER